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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,998	10/24/2005	Tadahiko Kato	TOYA117.005APC	1401

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
05/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,998	KATO ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/26/05 & 12/15/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Seikagaku Corporation (WO 02/04471 A1).

In claim 1, applicant claims "A therapeutic agent for nerve damage comprising, as an active ingredient, a low-molecular-weight saccharide comprising glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof. Seikagaku Corporation discloses applicant's agent or composition comprising a low-molecular-weight saccharide (hyaluronic acid oligosaccharide) comprising glucuronic acid and N- acetylglucosamine (see abstract). It should be noted that it is well settled that "intended use" of a composition or

product, e.g., for nerve damage, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Seikagaku Corporation agent or composition is the same as applicant's and should inherently have the same effect on nerve damage. Claim 2 which is drawn to the therapeutic agent according to claim 1, wherein the low-molecular-weight saccharide is a low-molecular-weight hyaluronic acid, is anticipated by Seikagaku Corporation, since Seikagaku Corporation's low-molecular-weight saccharide is a low-molecular-weight hyaluronic acid (hyaluronic acid oligosaccharide) (see abstract). It should be noted that Seikagaku Corporation low molecular weight hyaluronic acid comprises 4-60 saccharides (see abstract). Claim 3 which is drawn to the therapeutic agent according to claim 2, wherein the low-molecular-weight hyaluronic acid is hyaluronic acid disaccharide to hyaluronic acid 2,500-saccharide, is anticipated by Seikagaku Corporation, since Seikagaku Corporation's low-molecular-weight saccharide is a low molecular weight hyaluronic acid comprising 4-60 saccharides (see abstract). Claim 4 which is drawn to the therapeutic agent according to claim 3, wherein the low-molecular-weight hyaluronic acid is hyaluronic acid disaccharide to hyaluronic acid 50-saccharide, is anticipated by Seikagaku Corporation, since Seikagaku Corporation's low-molecular-weight saccharide is a low molecular weight hyaluronic acid comprising 4-60 saccharides (see abstract). Claim 5 which is drawn to the therapeutic agent according to claim 4, wherein the low-molecular-weight hyaluronic acid is hyaluronic acid tetrasaccharide, is anticipated by Seikagaku Corporation, since Seikagaku Corporation's low-molecular-weight saccharide is a low molecular weight hyaluronic acid comprising 4-60 saccharides (see abstract). Claim 6 which is drawn to the therapeutic agent according to claim 1, wherein nerve damage is caused by spinal cord injury or nerve trauma.

Seikagaku Corporation discloses applicant's agent or composition comprising a low-molecular-weight saccharide (hyaluronic acid oligosaccharide) comprising glucuronic acid and N-acetylglucosamine (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for nerve damage, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Seikagaku Corporation agent or composition is the same as applicant's and should inherently have the same effect on nerve damage.

Claims 1-2, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Atsuta et al. (JP 11140103 A).

In claim 1, applicant claims "A therapeutic agent for nerve damage comprising, as an active ingredient, a low-molecular-weight saccharide comprising glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof. Atsuta et al. disclose applicant's agent or composition comprising a low-molecular-weight saccharide (low molecular weight hyaluronic acid, 890,000) comprising glucuronic acid and N- acetylglucosamine (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for nerve damage, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Atsuta et al. agent or composition is the same as applicant's and should inherently have the same effect on nerve damage. Claim 2 which is drawn to the therapeutic agent according to claim 1, wherein the low-molecular-weight saccharide is a low-molecular-weight hyaluronic acid, is anticipated by Atsuta et al., since Atsuta et al.'s low-molecular-weight saccharide is a low-molecular-weight hyaluronic acid (see abstract). Claim 6 is drawn to the therapeutic agent

according to claim 1, wherein nerve damage is caused by spinal cord injury or nerve trauma. Atsuta et al. discloses applicant's agent or composition comprising a low-molecular-weight saccharide comprising glucuronic acid and N- acetylglucosamine (see abstract). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for nerve damage, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, Atsuta et al.'s agent or composition is the same as applicant's and should inherently have the same effect on nerve damage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atsuta et al. (JP 11140103 A).

In claim 7, applicant claims "A method of treating nerve damage, comprising administering an effective amount of a low-molecular-weight saccharide comprising at least glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof to an animal suffering from nerve damage.

Atsuta et al. disclose that a low-molecular-weight saccharide (low-molecular-weight hyaluronic acid) comprising at least glucuronic acid and N-acetylglucosamine can be used or administered to treat nerve damage (spinal cord injuries) (see abstract).

The difference between applicants' claimed method and the method of Atsuta et al. is that Atsuta et al. do not exemplify the use of said low molecular hyaluronic acid.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Atsuta et al. to administer Atsuta et al.'s low-molecular-weight saccharide (hyaluronic acid) agent or composition to treat nerve damage such as spinal cord injuries in a subject (such as an animal), since Atsuta et al.'s suggest that their agent or composition can be used to treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Atsuta et al. to administer Atsuta et al.'s low-molecular-weight saccharide (hyaluronic acid) agent or composition to treat nerve damage such as spinal cord injuries in a subject (such as an animal), since a skilled artisan would reasonable expect to use the composition taught by Atsuta et al. for the same said purpose.

In claim 8, applicant claims a method of manufacturing a therapeutic agent for nerve damage which comprises dissolving a low-molecular-weight saccharide comprising glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof in a solvent commonly used for drugs.

Atsuta et al. disclose an aqueous solution of low-molecular-weight saccharide (low-molecular-weight hyaluronic acid) comprising at least glucuronic acid and N-acetylglucosamine which can be used or administered to treat nerve damage (spinal cord injuries) (see abstract).

The difference between applicants' claimed method and the method of Atsuta et al. is that Atsuta et al. do not exemplify the method of preparation or manufacture of said saccharide (low-molecular-weight hyaluronic acid). However, Atsuta disclose that an aqueous solution of low-

molecular-weight saccharide (low-molecular-weight hyaluronic acid) can be prepared or manufactured. This implies that hyaluronic acid can be dissolved in water to form an aqueous solution. In fact, Atsuta et al. may have well prepared their solution their aqueous solutuion.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Atsuta et al. to prepare or manufacture Atsuta et al.'s aqueous hyaluronic acid agent or composition by dissolving low-molecular-weight saccharide (hyaluronic acid) in a water (a solvent commonly used for dissolving drugs) in order to use it to treat nerve damage such as spinal cord injuries in a subject (such as an animal), since Atsuta et al.'s suggest that their agent or composition can be used to treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Atsuta et al. to prepare or manufacture Atsuta et al.'s aqueous hyaluronic acid agent or composition by dissolving low-molecular-weight saccharide (hyaluronic acid) in a water (a solvent commonly used for dissolving drugs) in order to use it to treat nerve damage such as spinal cord injuries in a subject (such as an animal), since a skilled artisan would reasonable expect to use the composition taught by Atsuta et al. for the same said purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

SAJ 4/30/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

April 28, 2007.